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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,806	08/03/2001	Laurent Lecourt	S 5435	7152

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EXAMINER	
MENDOZA, MICHAEL G	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,806	LECOURT ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-14 and 16-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-14 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-8, 11-14, and 16-19 have been considered but are moot in view of the new ground(s) of rejection. The Applicant argues that Keller et al. does not teach combining O_2 with gaseous nitrogen protoxide with at least one active product selected from the group consisting of paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine, and morphine mimetics. However, Keller et al. does teach combining gaseous nitrogen protoxide with at least one active product selected from the group consisting of paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine, and morphine mimetics with the use of a metered dose inhaler (MDI). It is well know in the art of MDI's that atmospheric air containing oxygen is combined with the aerosol dispensed from a pressurized container.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-8, 11-14, and 16-19 are rejected under 35 U.S.C. 102(a) as anticipated by Keller et al. WO 00/06121 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Keller et al. WO/06121.

4. Keller et al. teaches a method for manufacturing an inhalable medicament or part of an inhalable medicament for the treatment or prevention of pain in humans or animals, comprising: combining O_2 (when used with a MDI, pg. 13, lines 25-28; translated in '958, col. 7, lines 19-22) and gaseous nitrogen protoxide (N2O) to at least on active product selected from the group consisting of paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine, and morphine mimetics; wherein the active product is chosen from among analgesics; wherein the active product is chosen from among compounds with an anti-inflammatory action; wherein the active product is chosen from among antipyretics (pgs. 15-17; translated in '958, col. lines 3-67 thru col. 9, lines 1-23); wherein the inhalable medicament further comprises a second gas selected from the groups consisting of helium, oxygen, nitrogen, xenon, hydrogen, carbon monoxide (CO), carbon dioxide (CO2), argon, krypton, nitrogen monoxide (NO), carbonated hydrocarbons, fluorocarbons, and mixtures of several of the gases (pg. 14, lines 21-30; translated in '958, col. 7, lines 48-57); wherein the inhalable medicament is in the form of an aerosol comprising the gas and the active product in the form of a powder, liquid or a powder/liquid mixture (pg. 18, lines 13-31; translated in '958 col. 9, lines 43-61); it would be inherent wherein the inhalable medicament contains a therapeutically effective

quantity of active product; it would be inherent wherein the combination of the at least one gas with the at least one active product leads to a synergistic effect; and wherein the inhalable medicament comprises O2 and N2O and at least one active product with an analgesic action (pgs. 15-17; translated in '958, col. lines 3-67 thru col. 9, lines 1-23).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8, 11-14, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. WO/06121 in view of Sosiak 6325062.

7. Keller et al. teaches a method for manufacturing an inhalable medicament or part of an inhalable medicament for the treatment or prevention of pain in humans or animals, comprising: combining gaseous nitrogen protoxide (N2O) to at least on active product selected from the group consisting of paracetamol, acetylsalicylic acid, arylcarboxylic acid, corticosteroids, mineralosteroids, non-steroidal anti-inflammatory drugs and their derivatives, codeine and its derivatives, morphine, and morphine mimetics; wherein the active product is chosen from among analgesics; wherein the active product is chosen from among compounds with an anti-inflammatory action; wherein the active product is chosen from among antipyretics (pgs. 15-17; translated in '958, col. lines 3-67 thru col. 9, lines 1-23); wherein the inhalable medicament further comprises a second gas selected from the groups consisting of helium, oxygen,

nitrogen, xenon, hydrogen, carbon monoxide (CO), carbon dioxide (CO2), argon, krypton, nitrogen monoxide (NO), carbonated hydrocarbons, fluorocarbons, and mixtures of several of the gases (pg. 14, lines 21-30; translated in '958, col. 7, lines 48-57); wherein the inhalable medicament is in the form of an aerosol comprising the gas and the active product in the form of a powder, liquid or a powder/liquid mixture (pg. 18, lines 13-31; translated in '958 col. 9, lines 43-61); it would be inherent wherein the inhalable medicament contains a therapeutically effective quantity of active product; it would be inherent wherein the combination of the at least one gas with the at least one active product leads to a synergistic effect; and wherein the inhalable medicament comprises O2 and N2O and at least one active product with an analgesic action (pgs. 15-17; translated in '958, col. lines 3-67 thru col. 9, lines 1-23). It should be noted that Keller et al. fails to specifically teach the step of combining O_2 with the claimed limitations.

8. Sosiak teaches an MDI using a common method for manufacturing an inhalable medicament comprising combining O_2 with an inhalable medicament. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the step of mixing O_2 with an aerosol for delivering aerosol into the respiratory tract of the user (col. 7, lines 24-26). Furthermore, it is well know in the art of MDI's that atmospheric air containing oxygen is combined with aerosol dispensed from a pressurized container.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn Dawson can be reached on (571) 272-4694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER